

REMARKS

Claims 1-14 and 16-38 are active in the present application.

Applicants wish to acknowledge the Examiner's indication that the elected species of claim 21 is allowed.

Applicants note that MPEP §707.07(f) clearly states:

“...an examiner must provide clear explanations of all actions taken by the examiner during prosecution of an application.”

MPEP §707.07(f) further states:

“Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it.”

In the present application the Examiner has complied with neither of these directives set forth in the MPEP. In fact, Applicants submit that it is clear that the Examiner has “cut and paste” the present Office Action (paper number 17) and the rejections therein from the previous Office Action mailed August 19, 2002 (paper number 12) and the Office Action mailed December 13, 2001 (paper number 8). Despite the repeated traversals set forth by the Applicants, the Examiner has remain steadfast in the present rejection without once offering any further explanation as to the deficiencies in the arguments present.

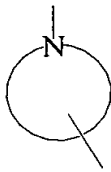
Based on the simple restatement of the rejection without any rebuttal offered in support of maintaining the current rejection, despite Office policy directing such a rebuttal (see above), it is Applicants understanding that the arguments below have not been considered. In fact, on page 2, line 11, the Examiner states: “Pharmaceutical drugs usually treat, not prevent disease.” However, the objectionable term “prevention” was removed from Claim 17 in the Amendment and Request for Reconsideration filed on June 12, 2002, and yet

this basis for rejection still remains more than a year and thousands of dollars later. Clearly, in view of the amendment to Claim 17 in June 12, 2002, the rejection of this claim is no longer tenable and, at the very least, the rejection of this claim should be withdrawn.

The rejection of Claims 1-14, 16-20, and 22-38 under 35 U.S.C. §112, first paragraph, is traversed.

Applicants once again wish to draw the Examiner's attention to the attached copy of Ex parte Breuer, 1 USPQ2d 1906 (Bd. Pat. App. & Inter. 1986), reviewing an Examiner's decision to reject claims under 35 U.S.C. § 112, first and second paragraph, for the alleged lack of enablement and indefiniteness of the terms "heterocycle" and "substituted" (id. at 1906-1907). In Breuer, the application in question disclosed how to make and use the claimed compounds, including 50 examples of the claimed compounds and a definition of both the terms "heterocycle" and "substituted" (id.). The U.S. Board of Patent Appeals reversed the Examiner's rejection based on the above facts in Ex parte Breuer found sufficient disclosure to enable a person having ordinary skill to practice the claimed invention without undue experimentation (id. at 1907).

Like Ex parte Breuer, the present specification provides a full definition of the term "heterocyclic" and/or derivatives of the term. Further, the present specification provides a full definition of the term "substituent" and/or derivatives of the term. Specifically, at page 14, line 1 to page 29, line 12, the Applicants fully disclose the acceptable variants of the R<sup>1</sup> (especially, N-containing cycloalkyl groups), R<sup>2</sup>, R<sup>3</sup>, A<sup>1</sup>, A<sup>2</sup>, and A<sup>3</sup> substituents, as well as the heterocyclic substituent of formula:



for use in the present invention. Also like Ex parte Breuer, the present specification discloses how to make the claimed compounds (page 4, line 21 to page 13, line 13 and at page 36, line 15 to page 47, line 24) and further provides nearly 250 examples of compounds having “heterocyclic” groups and “substituents” (see page 50, line 24 to page 165, line 11).

The Examiner asserts that “undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor” (paper number 17, page 4, lines 13-16). In Ex parte Breuer the Board did not find a patent including 50 examples of the claimed compounds to require undue experimentation or to have provided a “poor amount of direction.” Despite the precedent set in Ex parte Breuer, the Examiner concludes: “Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application” (paper number 17, page 4, lines 16-17). However, in view of the Board’s holding and their status as a precedential authority, Applicants ask how the Examiner can hold an application that provides nearly 250 examples of the claimed compound not to be enabled? Therefore, like in Ex parte Breuer, the Examiner’s rejection should be withdrawn.

Moreover, even in the absence of the clear precedent set by the Board in Ex parte Breuer, Applicants submit that the present application is enabled in yet a completely different manner.

MPEP §2164.04 states:

A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, *unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.*

Not only do the Applicants provide adequate disclosure to fully enable the skilled artisan to make the claimed compounds, Applicants have provided a test to enable the skilled artisan to assess the efficacy of the compounds made thereby (page 47, line 31 to page 48, line 17). Applicants also disclose preferred uses of the compounds of the present invention (page 48, line 19 to page 50, line 1). Moreover, the Examiner has not provided any reason whatsoever to “doubt the objective truth of the statements contained therein which must be relied on for enabling support.” Accordingly, this rejection is also unsustainable since the *Examiner has not met the burden* necessary to refute the adequacy of the present disclosure.

Further regarding Claim 17, it appears that the Examiner has merely reasserted the rejection under 35 U.S.C. §112, first paragraph, *in toto*, without regard for breadth of the rejection. The Examiner has remained silent with respect to this ground of rejection and Applicants argument thereto. In Applicants’ response of June 12, 2002, Applicants pointed to page 1, line 21 to page 2, line 10, which sets forth that platelet aggregation and thrombus formation are widely recognized to be causative of a series of disorders including, restenosis or reocclusion; the thrombus formation in case of vascular surgery, valve replacement, extracorporeal circulation or transplantation; disseminated intravascular coagulation; thrombotic thrombocytopenic; essential thrombocytosis; and inflammation. Accordingly, treatment of these disorders would be well within the purview of the skilled artisan with the present application in hand.

As is clearly evident above, Applicants have adequately enabled the present invention

and have disclosed how to make and use the compounds of the present invention thereby placing these compounds and their uses in the possession of the skilled artisan without undue experimentation. Therefore, with the present specification in hand, the skilled artisan would require nothing more than *routine* skill to realize the scope of the presently claimed invention, obtain the compounds of the present invention, practice the method of the present invention, and to assess the efficacy of the presently claimed compounds. The Examiner has not offered any evidence to refute these asserted facts, but rather has elected to merely recapitulate the previous rejections without the courtesy of providing any further evidence to support the rejection.

On page 4, lines 1-2 of paper number 17, the Examiner states: "the applicant has only provided one working example of the invention which is example 21." However, there is no requirement for Applicants to provide working examples (see MPEP §2164.02). Again, the Examiner has not provided any reason whatsoever to "doubt the objective truth of the statements contained therein which must be relied on for enabling support" as required by MPEP §2164.04.

For all the foregoing reasons, Applicants request withdrawal of this ground of rejection.

In view of the Examiner's repeated failure to comply with the directive of MPEP §707.07(f), as well as the fact that Applicants have not amended the claims in response to the outstanding rejections, Applicants believe that any future rejection should be presented in a non-final Office Action. Acknowledgement of this fact is requested.

Applicants submit that the application is in condition for allowance. Early notice to this effect is earnestly solicited.

Respectfully submitted,

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